

K06 3289

## 1.0 General Information

NOV 16 2006

Name and address of manufacturer: CHI LIN Technology CO., LTD.  
No.71, Te Lun Road, Jen Te Hsian,  
Tainan County 717, Taiwan, R.O.C.

Company Registration Number: Unknown (still under processing)

Contact Person: Mr. Phil Chen  
Ph: +886-6-279 - 4113 ext. 533  
Facsimile: +886-6-249 - 4751

Device Trade Name: 2MP Medical  
Monochrome Reference Display –  
MDM2130-2NC.

Device Common Name: Monochrome LCD Monitor, Monochrome  
Diagnostic Display, etc.

Classification of the Device: System, Image Processing, Radiological  
(CLASS II CFR 892.2050)

Intended Use: 2 MP Medical Monochrome Reference  
Display, MDM2130-2NC is intended to  
use in displaying images for review and  
analysis by trained medical practitioner  
for diagnose in CT, MRI, HIS and PACS.  
This device is not suitable for  
Mammography Digital System.

Predicate SE Device: MDM1900-1NG 19" Monochrome  
Medical Display by CHI LIN Technology  
CO., LTD. (K061303).

Standards:

2 MP Medical Monochrome Reference Display, MDM2130-2NC has met the following standards: Safety – UL 60601-1, EMC – EN 60601-1-2, ITE Safety/EMC – EN 60950-1, CE, FCC. It also meets CDRH recognized voluntary standard – DICOM (please refer to Appendix A for DICOM conformance statement and certificates, and Appendix B for other certificates and reports of other standards).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Chilin Technology Co., Ltd.  
% Mr. Marc M. Mouser  
Senior Project Engineer, Program Reviewer  
Underwriters Laboratories, Inc.  
2600 N.W. Lake Road  
CAMAS WA 98607-8542

NOV 16 2006

Re: K063289  
Trade/Device Name: Medical Display, MDM2130-2NC  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: October 25, 2006  
Received: November 1, 2006

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



*Protecting and Promoting Public Health*

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

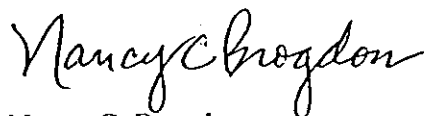
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K063289

Device Name: Medical Display, MDM2130-2NC

Indications For Use: 2MP Medical Monochrome Reference Display,  
MDM2130-2NC is intended to use in displaying images for review and analysis by  
trained medical practitioner for diagnose in CT, MRI, HIS and PACS. This device is  
not suitable for a digital mammography system.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K063289